

REMARKS

Formal Matters

Claims 18 and 19 remain pending in this application, and both of these claims have been rejected.

Obviousness-Type Double Patenting Rejection

The Office has not accepted the terminal disclaimer that Applicants filed on September 23, 2003. The Office, however, has not maintained the obviousness-type double patenting rejection. Applicants ask the Office to confirm that the obviousness-type double patenting rejection has been withdrawn and that the request for the terminal disclaimer is now moot.

Written Description Rejection Under 35 U.S.C. § 112, first paragraph

The Office has rejected claims 18 and 19 as allegedly lacking written description support in the specification. The Office has made this rejection because allegedly the structure of the claimed growth factor peptide has not been described. The Office asserts that, while the specification provides some examples of growth factor peptides, the claim allegedly only provides functional limitations.

Claim 18

Claim 18 is a product-by-process claim; in other words, it claims peptides obtained by a specific method. Applicants have argued that the claimed peptides may be obtained by following the process steps recited in the claims. Claim 18 does not

describe the properties of the peptide functionally, but instead describes the specific process steps that must be taken in order to isolate it.

The Office, in response, has cited two cases discussing composition claims. In the first case, *In re DiLeone*, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971), the claims at issue were composition claims that were ostensibly enabled, yet not supported by the written description. The Office points out, however, that in *DiLeone* the court states that in a situation where the “specification discusses *only* compound A and contains *no* broadening language of any kind . . . [it] might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B, and C has not been described.” (emphasis in original). The Office then attempts to analogize the current case to this hypothetical in *DiLeone*. This case is distinguishable from *DiLeone*’s hypothetical as Applicants disclose eight compounds—not merely one. Additionally, Applicants provide a common core structure, describing and broadening the class of compounds from the original eight disclosed. Claim 18 also describes the processes used to produce the claimed peptides. In contrast, *DiLeone*’s hypothetical described only one compound and did not contain broadening language further describing a class of compounds. The Office has misapplied this case.

Similarly, the Office cited *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993), for the proposition that written description of “a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.” The Office argues that *Fiers* shows that written description requires more than a method of obtaining a composition,

but it requires structural information. The Office, however, ignores the structural information provided in the specification and states “the Applicants have failed to provide any guidance as to the structure of the claimed peptide.” The specification provides a common core structure for the claimed peptides and eight examples of peptides meeting the limitations of these claims. Thus, significant structural information is provided in the specification, and apparently ignored by the Office. It is not necessary to incorporate the core structure into claim 18, as the written description inquiry focuses on the information provided by the Applicants in the specification, not just in the claims. M.P.E.P. § 2163(II)(A)(2).

Additionally, these cases both discuss that enablement of a composition is not sufficient to provide written description for a composition. Claim 18, however, is a product-by-process claim, where the limitations of the compositions are the actually processes taken to prepare it. This product-by-process claim is novel over the prior art based on the processes taken to prepare the peptides, and that those same processes are sufficient to describe the peptides, as they are what sets the claimed peptides away from the prior art. Thus, if the processes are sufficient to impart novelty to the claimed peptides, they must be sufficient to adequately describe it.

As these process limitations are sufficient to distinguish the claimed invention from the prior art, they must necessarily be sufficient to adequately describe the peptide. The fact that the claim has product-by-process limitations instead of traditional product limitations is of no moment. *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973) (stating that “[t]o the extent process limitations distinguish the *product* over the prior art,

they must be given the same consideration as traditional product characteristics”) (emphasis in original). Additionally, the specification provides detailed written description support, by providing a generic structure for the peptides and eight actual peptides based on that structure, falling within the scope of the pending claims.

Claim 19

Claim 19 is directed to plant growth factor peptides. The Office has argued that the physical properties described in the claim (such as solubility, acidity, and polarity) are not sufficient to distinguish it from prior art plant growth factors. The Office's statement, however, is confusing because the claims are not rejected over prior art—implying that the claimed properties must be sufficient to distinguish it from prior art plant growth factors.

These purely physical properties, however, in combination with items (c), (d), (e), (f), and (g) of claim 19 do distinguish the claimed peptide from the prior art. The MPEP states that identifying characteristics such as binding affinity, binding specificity, unique cleavage by a particular enzyme, a comparison of enzymatic activities, or antibody cross-reactivity can demonstrate possession of the invention. Thus, the other limitations of the claim (maintenance of activity after heating; elution through certain reversed-phase columns; inactivation by a proteolytic enzyme from *S. griseus*, but not by Glycosidases “mixed”; and adsorption to certain ion-exchange columns, but not others) provide additional information on the identifying characteristics of this invention showing that the inventors were in possession of the peptides of the invention. As

these properties distinguish the peptides from the prior art, they must also be sufficient to show they were in the possession of the inventors.

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002) considered under what specific circumstances functional language could support the written description. In that case, the claims were directed to nucleic acid probes that selectively hybridize to the DNA of *Neisseria gonorrhoeae*, when compared to a similar bacteria *Neisseria meningitides*. The patentee, Enzo, had identified three nucleic acid probes meeting the claim limitations and had deposited those probes. Enzo argued that the claims were supported by the written description because of the disclosed correlation of the function of hybridization with the bacterial DNA. *Id.* at 967. As strains of the two bacteria were publicly available and could be used to identify which probes would meet the limitations of the claims, the Federal Circuit stated that whether the claims were supported by the written description was a factual one and could not be decided against the patentee in summary judgment. In doing so, the Federal Circuit relied on the Written Description Guidelines issued by the U.S.P.T.O. The Guidelines state that written description can be met by

Show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

Id. at 964 (quoting Guidelines, 66 Fed. Reg. at 1106).

The Federal Circuit continued by describing an example provided in the Guidelines of claims to an isolated antibody to a known antigen, given the well defined

structural properties of antibodies, the functional characteristics of antibody-antigen binding, and the high level of scientific understanding in that particular field. *Id.* It concluded, before remanding the case, that the written description requirement would be met for all of the patent claims “if the functional characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitidis* were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed.” *Id.* *Enzo* requires that the Office consider all of the claim limitations—both the structural limitations and those describing a relationship between the function of the peptide and other known structures (such as standard chromatography resins). It is improper for the Office to ignore these limitations.

Like *Enzo*, in the present case the specification describes both structural and functional features of the claimed peptides, which are sufficient to distinguish those peptides from the prior art. The limitations of claim 19, not only describe physical properties such as the acidity of the peptide, but also describe the stability of the peptides under heated conditions and what types of resins the peptides will or will not bind to. The relationship of the peptides to the various resins provided in part (d) and (g) of claim 19 are analogous to the binding of the probes in *Enzo* to one bacterial strain, but not the other. This combination of structural and functional features having a disclosed correlation between that function and a sufficiently described structure is sufficient to provide written description support for this invention.

Finally, Office disputed the assertion that the specification discloses a sufficient number of species to provide written description support for the genus of peptides. The

specification provides eight different peptides, all with a related chemical structure, to support the genus. The law is clear that a representative number of species can provide written description support for a genus. What constitutes a “representative number” seems to be the key question for the Office. The MPEP states that “a ‘representative number’ is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.” MPEP § 2163 II.A.3.(a)(ii). The skilled artisan would recognize that application was in possession of the genus based on the disclosure of eight species sharing substantial portions of their chemical structure, in combination with the other properties of the claimed invention. Given the common core structure, the eight species are also sufficient to support the genus of peptides due to the homogeneity of the peptides and the number of examples provided. Thus, Applicants assert that the claimed invention is supported by the written description.

Applicants request that the Office withdraw both written description rejections.

Conclusion

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the Office's reconsideration and reexamination of the application, and the timely allowance of the pending claims. Should the Office wish to discuss the merits of this case, Applicants

invite the Office to telephone the undersigned representative at 202-408-4086. If there is any fee due in connection with the filing of this Response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 29, 2004

By: Rebecca McNeill
Rebecca M. McNeill
Reg. No. 43,796